

In The Matter Of:

In Re: Consolidated Steroid Injection Litigation Matters

Lloyd Saberski, M.D.

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21 **(Appearances Continued on Next Page)**

1 such as an infection. Infection is real. It's always
2 been real with these products, especially steroids.

3 The arachnoiditis is an imagined concern, a
4 theoretical concern. So the two issues here a real
5 legitimate medical concern, infection, versus something
6 that was theoretical. And on top of that, that
7 theoretical concern was put to bed years earlier.

8 Q. With respect to the risk of infection, what
9 is the risk of infection for an FDA approved steroid?

10 A. I do not know. But I will say this, I
11 don't -- well, none of the FDA approved products has
12 ever been associated with arachnoiditis when
13 administered in the epidural space.

14 Q. You don't know the risk of infection for FDA
15 approved products.

16 Correct?

17 MS. KASPUTYS: Objection.

18 BY MS. MITCHELL:

19 A. No. It's quite low. But I do know -- I
20 have some data related to that question. Certainly in
21 the period of time of prior to this outbreak, and

1 including this outbreak, there were 12 recorded
2 breaches that were found in the literature, I guess
3 that's between 2002 and 2012, pertaining to compounding
4 complications.

5 And during that same period of time, there's
6 zero from the manufactured side. So it's 12 to 0.
7 That's just a narrow band of time. I think, if you
8 look at it over decades, I think the manufacturing
9 industry has a stellar representation.

10 Q. Do you believe that the epidural space is
11 wholly separate from the subdural arachnoid space?

12 A. Well, this is an interesting concept.
13 Technically yes. It's called the blood brain barrier.
14 So everything in the epidural space and above is
15 outside the blood brain barrier.

16 However, at the microscopic level, there can
17 be communications. But traditionally, we can call it
18 the blood brain barrier. At a microscopic level, there
19 is some communication and movement. But basically, the
20 dura mater separates the central nervous system from
21 the rest of the body.

1 approved steroid preparations available.

2 The patient needs to be informed of any
3 benefit imagined, versus risks. As I said, there are
4 substantial risks in using a product that comes from a
5 compound or especially a parenteral product, and
6 especially if it does not have the benzyl alcohol or
7 some sort of preservative in appropriate concentration
8 to make it safer from pathogens.

9 Q. Forgive me if this is an answer, but you now
10 said substantial risks. What are the substantial risks
11 that you believe the patient needed to be advise of?

12 A. Infection.

13 Q. So if the providers in this case advised the
14 patients that there was a risk of infection, that would
15 comply, in your mind, with the standard of care?

16 A. Absolutely not. The risk of infection is so
17 much higher with a compounding pharmacist, to the point
18 where the patient needs to know what they're getting.
19 The instance related to infection from compounding
20 pharmacies was numerous between 2002 and 2012. Doctors
21 should be fully aware of that.

1 And it was published in our personal -- in
2 our literature, too, not just the lay press. It was in
3 our peer review magazines.

4 Q. Which magazines?

5 A. Oh, boy. I think it's Regional Anesthesia.
6 Maybe Anesthesia and Analgesia was the discussion
7 in 2000 -- oh, god. Anesthesia Analgesia.

8 Q. What year?

9 A. I think it might be 2008 or 2009.

10 Q. And you said this discusses the risks of
11 using compounding pharmacies?

12 A. Yes.

13 Q. Would you be able to locate that article and
14 provide the citation to counsel?

15 A. Probably.

16 Q. I'd ask that you kindly do that as well.

17 A. Yes. Would somebody write that down and
18 remind me?

19 MS. KASPUTYS: Sure.

20 BY MS. MITCHELL:

21 Q. You said that the risk is so much higher